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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/735,439

12/11/2003

Jacob Bar-Tana

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2054

7590

06/20/2006

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EXAMINER

ROYDS, LESLIE A

ART UNIT

PAPER NUMBER

1614

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/735,439	<b>Applicant(s)</b> BAR-TANA, JACOB	
	<b>Examiner</b> Leslie A. Royds	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 11 April 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 29-54 is/are pending in the application.
- 4a) Of the above claim(s) 34, 35, 40, 41, 47, 48, 53 and 54 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 29-33, 36-39, 42-46 and 49-52 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☒ Certified copies of the priority documents have been received in Application No. 09/915,412.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/11/03&amp;9/13/04</u> | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

#### **Claims 29-54 are presented for examination.**

Acknowledgment is made of the present application as a continuation application of U.S. Patent Application No. 09/915,412, filed July 25, 2001, now abandoned, which is a divisional application of U.S. Patent Application No. 09/104,880, filed June 25, 1998, now issued U.S. Patent No. 6,303,653. Acknowledgment is also made of Applicant's claim for priority under 35 U.S.C. 119(a-d) to Israeli Patent Application No. 121165, filed June 26, 1997, of which a certified copy has already been received and entered into U.S. Patent Application No. 09/915,412.

Applicant's Preliminary Amendment filed December 11, 2003 has been received and entered into the application. Accordingly, the specification at page 1 has been amended, claims 1-28 have been cancelled and claims 29-54 have been newly added. Applicant's subsequent Preliminary Amendment filed May 3, 2004 has also been received and entered into the application. Accordingly, the specification has been amended following the abstract and preceding the figures to include the sequence listing and has also been amended at page 13, lines 1-14 and 17-27. Applicant's Information Disclosure Statements (IDS) filed December 11, 2003 and September 13, 2004 have each been received and entered into the application. As reflected by the attached, completed copies of form PTO-1449 (11 pages total), the Examiner has considered the cited references, with the exception of the Limatta et al. reference cited at page 5 of the IDS filed December 11, 2003. This reference could not be located after a reasonable search by the Examiner and was, therefore, not considered. Applicant's response filed April 11,

2006 to the requirement for restriction/election dated March 6, 2006 has also been received and entered into the application.

***Preliminary Amendment filed May 3, 2004 Fails to Comply with 37 C.F.R. 1.121(b)(1)(ii)***

Applicant's Preliminary Amendment filed May 3, 2004 has been considered, but the amendment made to page 13 of the specification at lines 1-14 fails to comply with the standards set forth in 37 C.F.R. 1.121(b)(1)(ii) regarding the manner and form of amendments. In particular, it is noted that the amendment at page 13, lines 1-14, fails to set forth the entire full text of the paragraph to be amended. Applicant has only set forth the text of the portion of the paragraph that appears at page 13. In order to comply with 37 C.F.R. 1.121(b)(1)(ii), the full text of the paragraph as it begins at page 12, line 17, and ends at page 13, line 14, should be set forth as the full text of the paragraph to be amended with the appropriate mark-up to indicate what has been changed.

The text of 37 C.F.R. 1.121 governing amendments to the specification has been reproduced below for Applicant's convenience.

**"§ 1.121 Manner of making amendments in applications.**

(a) Amendments in applications, other than reissue applications. Amendments in applications, other than reissue applications, are made by filing a paper, in compliance with § 1.52, directing that specified amendments be made.

(b) *Specification.* Amendments to the specification, other than the claims, computer listings (§ 1.96) and sequence listings (§ 1.825), must be made by adding, deleting or replacing a paragraph, by replacing a section, or by a substitute specification, in the manner specified in this section.

(1) *Amendment to delete, replace, or add a paragraph.* Amendments to the specification, including amendment to a section heading or the title of the invention which are considered for amendment purposes to be an amendment of a paragraph, must be made by submitting:

(i) An instruction, which unambiguously identifies the location, to delete one or more paragraphs of the specification, replace a paragraph with one or more replacement paragraphs, or add one or more paragraphs;

(ii) The full text of any replacement paragraph with markings to show all the changes relative to the previous version of the paragraph. (emphasis added) The text of any added subject matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strikethrough cannot be easily perceived;

(iii) The full text of any added paragraphs without any underlining; and

(iv) The text of a paragraph to be deleted must not be presented with strike-through or placed within double brackets. The instruction to delete may identify a paragraph by its paragraph number or include a few words from the beginning, and end, of the paragraph, if needed for paragraph identification purposes.

Appropriate correction to the amendment for compliance with 37 C.F.R. 1.121(b)(1)(ii) should be made and resubmitted to the Office for consideration.

#### ***Requirement for Restriction/Election***

Applicant's election **with traverse** of the invention of Group I (claims 29-35), drawn to a method for the treatment of Syndrome X comprising the oral administration to a human subject of an effective amount of a xenobiotic fatty acid compound, and the election of 3,3,14,14-

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tetramethyl-hexadecane-1,16-dioic acid as the species of xenobiotic fatty acid compound, in the reply filed April 11, 2006, is acknowledged. Applicant's traversal is on the grounds that the present invention relates to novel methods of treating Syndrome X, which comprises some or all of dyslipoproteinemia (which itself manifests hypercholesterolemia-hypertriglyceridemia and low HDL cholesterol), obesity, impaired glucose tolerance, essential hypertension and thrombogenic/fibrinolytic defects, such that successful treatment of any of these conditions would result in improvement of Syndrome X. Thus, Applicant states on the record that Groups I-IV are not independent and that there would not be a serious burden on the Examiner if restriction were not required (see page 7 of Applicant's remarks).

Applicant's traversal regarding the present requirement for restriction among the inventions designated as Groups I-IV has been carefully considered and is persuasive. In light of such, the requirement for election has been hereby **withdrawn** and the inventions of Groups I-IV will be examined together.

Applicant is reminded that should he traverse on the ground that the inventions are not patentably distinct and clearly admits on the record that this is the case, if the Examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention. Please see page 6 of the previous Office Action dated March 6, 2006. Applicant states at page 7 that, "As disclosed in the instant specification, this invention relates to novel methods of treating Syndrome X, which comprises some or all of dyslipoproteinemia (which itself manifests hypercholesterolemia-hypertriglyceridemia, and low HDL-cholesterol), obesity, impaired glucose tolerance, essential hypertension and thrombogenic/fibrinolytic defects (see, for example, page 10, last full

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paragraph, of the subject specification). *Therefore, successful treatment of any of these conditions would result in improvement of Syndrome X. Accordingly, applicants maintain that Groups I-IV are not independent and restriction is not proper.*”(emphasis added) In light of such a statement, should the Examiner find prior art on the use of the elected species of xenobiotic fatty acid for the treatment of any one of the therapeutic uses defined in Groups II-IV, such an admission would be relied upon under 35 U.S.C. 103(a) as evidence stated clearly on the record that the elected species would necessarily have been effective at improving and/or treating Syndrome X, as already acknowledged by Applicant.

Insofar as Applicant has failed to formally traverse the election of species requirement, the requirement for election of a single species of xenobiotic fatty acid compound remains proper for the reasons already made of record at pages 4-5 of the previous Office Action dated March 6, 2006 and is hereby made **FINAL**.

Claims 34-35, 40-41, 47-48 and 53-54 are **withdrawn** from further consideration pursuant to 37 C.F.R. 1.142(b), as being to non-elected inventions, there being no allowable generic or linking claim.

The claims corresponding to the elected subject matter are 29-33, 36-39, 42-46 and 49-52 and such claims are herein acted on the merits.

### ***Objection to the Specification***

The application is objected to because of alterations which have not been initialed and/or dated as is required by 37 CFR 1.52(c). Applicant's attention is directed specifically to the changes made at page 10, line 12, of the present specification.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 29-33, 36-39, 42-46 and 49-52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bar-Tana ("Long Chain Dicarboxylic Acids: Hypolipidaemic, Antiobesity and Antidiabetic Activity", New Antidiabetic Drugs, 1990; cited by Applicant) in view of Hertz et al. ("Mode of Action of Peroxisome Proliferators as Hypolipidemic Drugs", *Journal of Biological Chemistry*, 1995; cited by Applicant), Ferrannini et al. ("Hyperinsulinaemia: The Key Features of a Cardiovascular and Metabolic Syndrome", *Diabetologia*, 1991).

Bar-Tana teaches the administration of MEDICA 16 (last paragraph at page 158, lines 1-2), a  $\beta,\beta'$ -methylsubstituted hexadecanedicarboxylic acid of 16 carbon atoms in length of the chemical formula  $\text{HOOC-CH}_2\text{-C}(\text{CH}_3)_2\text{-(CH}_2\text{)}_{10}\text{-C}(\text{CH}_3)_2\text{-CH}_2\text{-COOH}$ , a long chain dicarboxylic acid with a  $\omega$ -carboxyl function that allows for ATP-dependent CoA-thioesterification into the respective CoA-thioester at either carboxylic end (lines 4-9 from top of page 158), to rats (last paragraph at page 158, lines 1-2; see present claims 42-46 and 49-52), for a 50-70% decrease in plasma triacylglycerol and a 40-50% decrease in plasma cholesterol (last paragraph at page 158, lines 3-5; see present claims 42-46), and a corresponding 1.5-fold increase in HDL-cholesterol/(VLDL+LDL)-cholesterol ratio (lines 2-4 from top of page 159; see present claims 49-52) when treated orally (last paragraph at page 158, lines 3-5; see present claims 42 and 49).



The differences between the Bar-Tana reference and the presently claimed subject matter lie in that the reference fails to teach the treatment of dyslipoproteinemia (see present claims 36-39), which Applicant defines at page 10, lines 23-24 as “combined hypercholesterolemia-hypertriglyceridemia”, Syndrome X (see present claims 29-33), or administration of the dicarboxylic fatty acid, 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid, to a human subject (see present claims 29, 36, 42 and 49).

However, the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains because it would have been *prima facie* obvious to the skilled artisan that a therapeutic agent that has already shown efficacy in reducing plasma triglycerides and plasma cholesterol would necessarily have been suggestive of the same level of efficacy in treating the disorder of “dyslipoproteinemia”, and used and defined in the present claims as combined hypertriglyceridemia and hypercholesterolemia (please see page 10, lines 23-24). The skilled artisan would have been motivated to administer the compound 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid to a subject have combined hypertriglyceridemia and hypercholesterolemia because the compound was known to successfully reduce plasma levels of both triglycerides and cholesterol such that one of ordinary skill in the art would have reasonably expected success in treating a condition characterized by abnormally elevated levels of both triglycerides and cholesterol.

In addition, Hertz et al. is relied upon in support of this conclusion for its teaching that, “Aryloxyalkanoic fibrates (e.g. clofibrate (1) and bezafibrate (2)), substituted long chain

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dicarboxylic acids (e.g. Medica 16 (3,4)), and other amphipathic carboxylates lower plasma triglycerides and cholesterol levels, and some are extensively used in humans as drugs of choice for treating hypertriglyceridemia or combined hypertriglyceridemia/hypercholesterolemia.” (see line 1-6 of the second paragraph at column 1 of page 13470) Such a teaching would have provided the reasonable expectation of success that the 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid would have efficacy in treating combined hypertriglyceridemia and hypercholesterolemia (i.e., “dyslipoproteinemia” as defined by Applicant).

Furthermore, the efficacy of the compound 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid in reducing plasma triglycerides and plasma cholesterol and increasing HDL/(VLDL+LDL) cholesterol ratio would have been reasonably suggestive of the same or a substantially similar level of efficacy in treating Syndrome X. As taught by Ferrannini et al., syndrome X is characterized by the concomitant occurrence of any one or more of insulin resistance, glucose intolerance, hypertension and dyslipidaemia (see paragraph bridging columns 1-2 of page 416). In particular, Ferrannini et al. states, “Recently, it has been suggested that hyperinsulinaemia may be the common element accounting for the association of obesity, Type 2 diabetes, and hypertension...This has led Reaven [9] to hypothesise that insulin resistance aggregates with glucose intolerance, hypertension, and dyslipidaemia in a distinct syndrome (syndrome X).” (see paragraph bridging columns 1-2 of page 416) In light of such a teaching, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that the efficacy shown by the compound 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid in treating derangement of plasma lipids (i.e., triglycerides and cholesterol) would necessarily have had efficacy in treating Syndrome X, since Syndrome X was known in the art to be characterized by

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lipid dysfunction. As a result, the skilled artisan would have reasonably expected that the treatment of a symptom or condition necessarily associated with the overall condition of syndrome X would have necessarily resulted in amelioration of the overall syndrome itself.

Moreover, Applicant admits on the record that such is the case. In particular, Applicant remarks at page 7 of the response filed April 11, 2006, "As disclosed in the instant specification, this invention relates to novel methods of treating Syndrome X, which comprises some or all of dyslipoproteinemia (which itself manifests hypercholesterolemia-hypertriglyceridemia, and low HDL-cholesterol), obesity, impaired glucose tolerance, essential hypertension and thrombogenic/fibrinolytic defects (see, for example, page 10, last full paragraph, of the subject specification). *Therefore, successful treatment of any of these conditions would result in improvement of Syndrome X.*"

Despite the fact that the cited references to Bar-Tana and Hertz et al. concern the administration of the fatty acid 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid to rats, it is well recognized in the art that *in vivo* studies in animals, such as mice or rats, commonly precede testing of pharmaceutical agents in humans. *In vivo* studies serve as a reasonable predictor of efficacy in a human model by providing a basis for determining the efficacy of such an agent in a similar physiological environment *in vivo* and extrapolating such efficacy to a genetically similar animal model. Although Bar-Tana and Hertz et al. teaches the efficacy of the compound 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid *in vivo* for reducing plasma triglycerides, plasma cholesterol and raising the HDL/(VLDL+LDL) cholesterol ratio in rats, such results raise the reasonable expectation of success that such a compound would have been reasonably expected to have the same or substantially similar activity *in vivo* in humans, absent factual

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evidence to the contrary. In fact, Bar-Tana expressly suggests that, "The overall pharmacological effect in rodents appears to point to the potential use of these drugs in the treatment of hyperlipaemic-obese-diabetic syndromes." Such a teaching is undoubtedly a suggestion to adapt the agent for therapeutic use *in vivo* in humans with the reasonable expectation of substantial efficacy in treating disorders associated with lipid dysfunction.

### ***Double Patenting***

#### **Obviousness-Type Double Patenting**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

#### **Provisional Rejection**

Claims 36-39, 42-46 and 49-52 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-34 of copending U.S. Patent Application No. 10/735,452.

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An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the copending claims and those of the present application are not considered to be patentably distinct from each other because the present claims render the copending claims obvious. The present claims clearly provide for the treatment of dyslipoproteinemia, lowering plasma triglyceride levels and increasing HDL cholesterol comprising administering an effective amount of 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid to a human subject. Although the copending claims recite a limitation wherein the therapeutically effective amount also inhibits HNF-4 controlled gene transcription, this is not considered a patentable distinction between the copending claims and the present claims because the identical compound is taught in an identical amount for an identical therapeutic use and, therefore, any subsequent function of the compound in inhibiting HNF-4 controlled gene transcription is considered to be a function that is necessarily present, although not expressly stated, in the compound of the instant claims.

Accordingly, rejection of present claims 36-39, 42-46 and 49-52 is deemed proper over claims 29-34 of copending U.S. Patent Application No. 10/735,452 as claiming obvious and unpatentable variants thereof.

**Non-Provisional Rejections**

Claims 36-39, 42-46 and 49-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 19 of U.S. Patent No. 4,689,344 in view of Bar-Tana ("Long-Chain Dicarboxylic Acids: Hypolipidaemic, Antiobesity and Antidiabetic Activity", New Antidiabetic Drugs, 1990; cited by Applicant).

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the copending claims and those of the present application are not considered to be patentably distinct from each other because the patented claims anticipate the present claims. In particular, while it is noted that the patented claims clearly provide for the administration of the compound 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid for reducing serum cholesterol in a patient in need of said therapy, Bar-Tana teaches that the compound 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid was known in the art to reduce plasma triglycerides, in addition to cholesterol, as well as increase the HDL/(VLDL+LDL) cholesterol ratio (please see lines 2-4 from the top of page 159). In light of such, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention that the administration of this identical compound to an identical host would have necessarily resulted in the reduction of serum triglycerides and an increase in HDL/(VLDL+LDL) cholesterol, regardless of whether such properties of the compound had been recognized by the patentee at the time of the invention.

Accordingly, claims 36-39, 42-46 and 49-52 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 5 and 19 of U.S. Patent No. 4,689,344 as claiming obvious and unpatentable variants thereof.

Claims 29-33 are rejected under the judicially created doctrine of obviousness-type double patenting over claims 1-3 and 8 of U.S. Patent No. 6,303,653.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claims because the examined claim is either anticipated by, or would have been obvious over, the reference claims.

Although the conflicting claims are not identical, the copending claims and those of the present application are not considered patentably distinct from each other because the present claims anticipate the patented claims. In particular, the present claims clearly provide for the administration of 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid, a xenobiotic fatty acid compound capable of being converted to its respective coenzyme A thioester, to a human subject for the treatment of Syndrome X. While the patented claims are drawn to the genus of xenobiotic amphipathic carboxylates convertible to its respective CoA thioester, it is noted that the recitation of a species, in this case, 3,3,14,14-tetramethyl-hexadecane-1,16-dioic acid, will always anticipate the larger genus. Please reference MPEP §2131.02 for a discussion of genus-species situations and also *In re Slayter*, 276 F.2d 408, 411, 125 USPQ 345, 347 (CCPA 1960) and *In re Gosteli*, 872 F.2d 1008, 10 USPQ2d 1614 (Fed. Cir. 1989).

Accordingly, claims 29-33 are rejected under the judicially created doctrine of

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obviousness-type double patenting as being unpatentable over claims 1-3 and 8 of U.S. Patent No. 6,303,653 as claiming obvious and unpatentable variants thereof.

### ***Conclusion***

Rejection of claims 29-33, 36-39, 42-46 and 49-52 is deemed proper.

Claims 34-35, 40-41, 47-48 and 53-54 are withdrawn from consideration pursuant to 37 C.F.R. 1.142(b).

No claims of the present application are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leslie A. Royds whose telephone number is (571)-272-6096. The examiner can normally be reached on Monday-Friday (9:00 AM-5:30 PM).


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin H. Marschel can be reached on (571)-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Leslie A. Royds  
Patent Examiner  
Art Unit 1614

June 5, 2006



ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER